

GRADIENT SEQUENTIAL COMPRESSION SYSTEM FOR
PREVENTING DEEP VEIN THROMBOSIS

Cross-Reference to Related Application

This application is a continuation-in-part to Application Serial No. 08/751,170, filed November 15, 1996, which is a continuation-in-part to Application Serial No. 08/233,429, filed April 5, 1994, now U.S. Patent No. 5,575,762, which is hereby incorporated herein by reference.

Field of the Invention

The present invention relates to therapeutic medical devices and methods, and more particularly to devices and methods for improving venous blood flow in a patient.

Background of the Invention

Deep vein thrombosis (DVT) and pulmonary embolism (PE) constitute major health problems in the United States. It has been estimated that 300,000 to 600,000 hospitalizations a year are attributable to DVT and PE conditions. Venous thromboembolism is also a significant risk in surgical patient populations where preoperative, operative and postoperative immobilization with concomitant loss of venous pump function causes blood stasis.

The use of prophylactic antithrombotic drugs for preventing DVT are known to the art. However, the efficacy of prophylactic administration of anticoagulants and antiplatelet agents has been disputed, and is certainly not absolute. An alternative approach, attractive because of its freedom from hemorrhagic side effects, is the use of physical

techniques such as elastic stockings, passive leg exercise, electrical calf stimulation and external pneumatic compression of the legs. Pneumatic compression has been the most studied and appears to be an effective therapeutic technique. For example, the results of a comparison trial between sequential compression and uniform compression are disclosed in article by E.W. Salzman, et al., entitled *Effect of Optimization of Hemodynamics on Fibrinolytic Activity and Antithrombotic Efficacy of External Pneumatic Calf Compression*, Annals of Surgery, Vol. 206, No. 5, November (1987), pp. 636-641. Salzman et al. also discloses the lack of commercially available systems for applying external pneumatic compression in an optimized manner, based on blood flow velocity and volumetric flow rate, etc. Antithrombotic modalities based on sequential pneumatic compression are also disclosed in articles by J.A. Caprini, et al., entitled *Role of Compression Modalities in a Prophylactic Program for Deep Vein Thrombosis*, Seminars in Thrombosis and Hemostasis, Vol. 14, Supp., Thieme Medical Publishers, Inc., pp. 77-87, (1988); and Hull, et al., entitled *Effectiveness of Intermittent Pneumatic Leg Compression for Preventing Deep Vein Thrombosis After Total Hip Replacement*, Journal of the American Medical Association, Vol 263, No. 17, May, 2, 1990, pp. 2313-2317. Devices for performing sequential compression have also been patented. For example, U.S. Patent No. 4,396,010 to Arkans, discloses a time-based sequential compression device for simultaneously inflating multiple limb sleeves. Time-based sequential compression devices are also publicly available from The Kendall Company, of Massachusetts. For example, FIG. 1 illustrates an experimentally derived graph of an inflation cycle for a Model 5325 sequential compression device, manufactured by The Kendall Company. It is believed, however, that none of these

sequential compression devices and methods provide for optimum blood flow velocity and volumetric flow rate in recumbent patients.

Thus, notwithstanding these attempts to develop compression devices for preventing deep vein thrombosis and pulmonary embolism, there continues to be a need for a gradient sequential compression system which provides a high blood flow velocity and a highly therapeutic prophylactic modality to limbs of a recumbent user.

Summary of the Invention

It is therefore an object of the present invention to provide a system and method for reducing the occurrence of deep vein thrombosis (DVT) and pulmonary embolism in recumbent users.

It is also an object of the present invention to provide a system and method for achieving a high venous blood flow rate in a limb of a user.

It is another object of the present invention to provide a system and method of sequentially establishing a gradient of compressive forces, which is pressure-based.

It is a further object of the present invention to provide a system and method of regulating a gradient of compressive forces, using real-time feedback.

It is still a further object of the present invention to provide a system and method of providing a prophylactic modality to limbs of a user in an alternating sequence.

It is another object of the present invention to provide a system and method for determining the selected mode of operation used for achieving a high venous blood flow rate in a body portion of a user based on the type of compression sleeve or the particular body portion to be treated.

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invention to provide a universal connecting device and method that identifies a mode of operation associated with a connector mated thereto and provides a signal indicative of the mode of operation to the system such that the system may be automatically configured to the selected mode of operation.

These and other objects, features and advantages of the present invention are provided by a compression system and method which provides cyclical squeezing and relaxing action to one or more limbs of a user. This occurs by sequentially establishing a decreasing gradient of compressive forces along the limbs in a proximal direction. In particular, the compression system includes one or more sleeves (e.g., calf, thigh, calf and thigh, arm, forearm, torso, etc.) which can be wrapped around and releasably secured to a limb(s) of a user. The sleeves have one or more inflatable chambers therein for retaining pressurized air upon inflation and for applying a compressive force to a limb. The compression system also includes a system controller for controlling transfers of pressurized air from an external or internal source to the inflatable chambers of the sleeves during respective inflation cycles, and for venting the pressurized air during respective deflation cycles. Transfers of air from the system controller to the sleeves are preferably provided by pneumatic connecting means which can include first and second conduit means. First and second conduit means preferably include a plurality of separate conduits or conduit ribbon.

According to one embodiment of the present invention, the system controller includes control means and first and second pluralities of feeder valves, responsive to control means, for enabling and disabling transfers of air from the source to respective ones of the inflatable chambers. Control means is provided for controlling the sequence by which the feeder valves are

directionally opened and closed so that during an inflation cycle a gradient of compressive forces can be sequentially established and maintained along a limb of a user for a predetermined time interval. In

5 particular, according to a first embodiment, control means is provided for opening only one of the feeder valves to the source of pressurized air at a time, so that each of the inflatable chambers is independently inflated and regulated (e.g., measured and adjusted).
10 Control means preferably includes a pressure transducer and means coupled thereto for sampling the pressures in each of the inflatable chambers and adjusting the pressures based on the samples so that the chambers are maintained at predetermined pressures, even if the limb
15 sleeves are relatively loosely or tightly wrapped or the position of the limb is adjusted during treatment.

According to an aspect of the first embodiment of the present invention, the system controller includes first and second intermediate
20 valves, connected between the source and the respective first and second pluralities of feeder valves. The intermediate valves, which are responsive to control means as well, enable transfer of air from the source to the first and second pluralities of feeder valves
25 during respective first and second inflation cycles and vent air from the first and second pluralities of feeder valves during respective deflation cycles. In particular, the feeder valves and intermediate valves are directionally opened and closed to facilitate
30 inflation, measurement and adjustment of the pressures in the limb sleeves.

The system controller also preferably includes means for sensing whether pneumatic connecting means is attached thereto. Sensing means may include
35 an infrared, Hall effect or reflective sensor(s), for example. Control means also includes means, responsive to the sensing means, for automatically adjusting from

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a default two-limb mode of operation to a one-limb mode by preventing the occurrence of either the first or second inflation cycles if the respective first or second conduit means is disconnected from the system controller. The first and second inflation cycles are preferably 180° out of phase so that only one limb sleeve is being inflated at a time.

According to another aspect of the present invention, the sensor also determines the selected mode of operation to be used by the controller. As stated previously, the current invention utilizes different compression sleeves. These compression sleeves contain different numbers of inflation chambers and are formed differently to conform to and adequately compress selected portions of the body (i.e., calf, thigh, calf and thigh, arm, forearm, torso, ect.). Further, the system utilizes different pressure cycles for providing treatment to different body portions. The controller of the present invention determines the proper mode of operation for the system by using a sensor. This sensor senses an indication from an indicator connected to the compression sleeve being used by the system. This indicator designates the mode of operation associated with the sleeve. In this embodiment, the sensor provides a signal to the controller that identifies the selected mode of operation indicated by the sleeve. The controller configures the system in accordance with this signal to operate in the selected mode of operation. This, in turn, allows for the automatic configuration of the controller for a selected treatment without the need for user input.

The system controller also includes means for detecting low and high pressure fault conditions which can be caused by disconnected or occluded conduits, and sleeves that are wrapped too loosely or too tightly about a limb.

According to yet another aspect of the

invention, compressive forces are applied to a limb of a user by sequentially compressing a distal portion and then a relatively proximal portion of the limb to provide respective first and second radially inwardly directed compressive forces thereto. The first compressive force is maintained above the second compressive force so that a decreasing pressure gradient is established in a proximal direction along the limb for a preselected time interval. The force is preferably maintained by measuring the compressive forces and adjusting (i.e., increasing or decreasing) the compressive forces to maintain predetermined forces.

More particularly, the invention includes a method of applying compressive forces to a limb of a user using a multi-chambered inflatable limb sleeve surrounding the limb. The method includes the steps of pressurizing a first chamber of the limb sleeve to a first predetermined chamber pressure and then pressurizing a second chamber, disposed proximally relative to the first chamber, to a second preselected chamber pressure, after the first chamber reaches a first threshold pressure. The first threshold pressure may be less than or equal to the first predetermined pressure.

Preferably, the second chamber pressurizing step occurs after a pressure in the first chamber has been established at the first predetermined pressure for at least a first time interval. A step is also performed to regulate the pressures in the first and second chambers at their respective predetermined pressures so that a constant pressure gradient is established therebetween. The regulating step may include the steps of measuring a pressure in the first chamber while preventing depressurization of the second chamber and vice versa. Additionally, the regulating step may include the steps of measuring a pressure in

5 The pressures in the chambers may also be
adjusted by performing periodic reinflating steps (and
also deflating steps). Similar steps may also be
performed to inflate third and fourth, etc. chambers of
the limb sleeve, in sequence, so that a monotonically
0 decreasing pressure gradient is established and
maintained in a proximal direction between the chambers
of a sleeve(s).

According to a second embodiment of the present invention, each of the feeder valves described with respect to the first embodiment are replaced by a pair of filling and monitoring valves. The filling valves are preferably normally-closed valves and the

monitoring valves are preferably normally-open valves. Here, the filling valves have an open state for enabling one-at-a-time transfer of pressured air from a source to the inflatable chambers of the first and second limb sleeves, in response to application of an energizing signal (e.g., logic 1), and a normally-closed blocking state which disconnects a respective chamber from the air source. In contrast, the monitoring valves have a normally-open state for enabling transfer of pressurized air from a respective inflatable chamber to an output thereof. These outputs are preferably pneumatically coupled through a corresponding three-way normally-open intermediate valve to a vent "V" or a pressure transducer in response to appropriate control signals. The monitoring valves also have a closed state (which can be achieved by application of an energizing signal (e.g., logic 1)) to prevent the escape of pressured air from a respective chamber when other chambers are being inflated or when the pressures in other chambers are being independently measured.

Control means, which is operatively connected to the filling, monitoring and intermediate valves, is provided for inflating a first inflatable chamber of the first limb sleeve by disposing the corresponding filling valve in an open state and the other filling valves in their respective normally-closed states. During inflation of the first inflatable chamber, the corresponding first monitoring valve is also disposed in a normally-open state so that the pressure in the first inflatable chamber can be measured in real time as it is being inflated and thereafter when the first inflatable chamber is fully inflated and the corresponding filling valve has been closed. Thus, in contrast to the first embodiment, the pressure in a chamber can be continuously measured as the chamber is being inflated to its respective predetermined

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pressure. This provides real-time feedback of the chamber pressure. Preferably, this real-time feedback is used by the control means to adjust the inflation time of the respective chamber during the current or subsequent inflation cycle(s). The amount of time needed to measure the pressure in a chamber after the respective filling valve closes can also be reduced because the pneumatic connecting lines between the respective monitoring valve and the pressure transducer will already be at least partially pressurized at the respective chamber pressure when the measurement operation commences.

Brief Description of the Drawings

FIG. 1 is a graph illustrating an inflation cycle of a three chamber compression system, according to the prior art.

FIG. 2 is a perspective view of a system controller according to an embodiment of the present invention.

FIG. 3A is a graph illustrating first and second inflation cycles, according to the present invention.

FIG. 3B is a flow chart illustrating the operations performed by a system controller according to an embodiment of the present invention, during the first and second inflation cycles illustrated by FIG. 3A.

FIG. 4 is a schematic diagram illustrating a compression system according to a first embodiment of the present invention.

FIG. 5 is a perspective view of a valve manifold and associated hardware connected thereto.

FIG. 6A is a perspective view of a preferred pneumatic connecting means utilized by the present invention.

FIG. 6B is a cross-sectional view of the pneumatic connecting means according to FIG. 6A, taken

along the lines 6B-6B'.

FIG. 7 is a schematic diagram illustrating a compression system according to a second embodiment of the present invention.

5 FIG. 8 is a perspective view of a universal connecting device according to one embodiment of the invention, wherein the device includes an optical signal generator.

10 FIG. 9 is a perspective view of a universal connecting device according to another embodiment of the invention.

FIG. 10 is a flow chart illustrating the operations performed by the universal connecting device according to an embodiment of the present invention.

15 FIG. 11A is perspective view of a universal connecting device including a Hall Effect sensor according to another embodiment of the invention.

20 FIG. 11B is an exploded perspective view of a connector for connecting to the universal connecting device according to another embodiment of the invention.

Fig. 12 is a perspective view of a universal connecting device according to an embodiment of the present invention.

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Description of a Preferred Embodiment

30 The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of a compression system and method are shown and described. This invention may, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these
35 embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Like numbers refer to like elements throughout.

Referring now to FIG. 2, a first embodiment of a system controller 10 according to the present invention will be described. The system controller 10 includes a housing formed by top and bottom housing portions 13 and 11, respectively. The top housing portion 13 may include an on/off switch 12 and a sloped display 15, such as an LED display or a more preferable liquid crystal display (LCD), for visually communicating chamber inflation information (e.g., pressure levels, chamber status), the mode of operation (e.g., one- or two-limb mode; and 2, 3 or 4-chamber mode, calf, thigh, calf and thigh, foot, arm, forearm, torso, ect.) and alarm, alert and fault conditions. The display may also provide means, responsive to actuation by a user or health care professional, for preselecting the desired pressure levels to be achieved during a sleeve inflation cycle. Based on experiment, it was determined by the inventors herein that pressures ranging from 65-15 mmHg are most preferred.

The system controller 10 may also include an internal source of pressurized air 20 such as a compressor, however, an external pneumatic fitting or similar device (not shown) may be provided adjacent the controller housing for connecting the controller 10 to an external source of pressurized air. A bracket 19 is also provided for securing an electrical cord (not shown) during periods of nonuse.

The system controller 10 also preferably includes a valve manifold 30 having a plurality of valves which facilitate inflation of limb sleeves 22 and 24. As illustrated by FIG. 4, the limb sleeves are preferably four-chamber sleeves. Alternatively, a plurality of single-chamber sleeves may be provided as an equivalent substitute for a multi-chamber sleeve. The valves in the manifold 30 are also directionally coupled and controlled to facilitate measurement and adjustment of pressures in the limb sleeves 22, 24, as

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explained more fully hereinbelow with respect to FIGS. 4 and 7. Preferred means 50 for pneumatically connecting the system controller 10 to the limb sleeves is also illustrated by FIGS. 6A-6B. Pneumatic connecting means 50 preferably comprises first and second conduit means 54, such as a plurality of flexible conduits or conduit ribbon 56, as illustrated in FIG. 6B. These and other preferred features of the sleeves 22, 24 and connecting means 50 are disclosed in commonly assigned U.S. Patent Des. 376,013, to Sandman et al. entitled *Compression Sleeve for Deep Vein Thrombosis*, and U.S. Patent No. 5,588,954, to Ribando et al. entitled *Connector for a Gradient Sequential Compression System*, the disclosures of which are hereby incorporated herein by reference.

Referring now to FIGS. 3A-3B, a preferred method of applying compressive forces to a limb of a user using a multi-chambered inflatable limb sleeve includes inflating (i.e., pressurizing) a first chamber of the limb sleeve to a first predetermined chamber pressure, shown as 50 mmHg, during a first inflation cycle (shown by solid lines). As will be understood by those skilled in the art, pressurization of a chamber causes a compression of the limb and provides a radially inwardly directed compressive force about the circumference of the limb. The predetermined chamber pressures may be user selected at the display, however respective default pressures are preferably fixed by the controller 10. Thereafter, at time B, a second chamber of the sleeve, which is disposed proximally relative to the first chamber, is pressurized to a second predetermined pressure level, shown as 45 mmHg, by time C. Time B preferably occurs after the pressure in the first chamber reaches a threshold pressure, and more preferably after the first chamber pressure has been established at a respective predetermined pressure for a predetermined time interval. The threshold

pressure may be less than or equal the first predetermined pressure of 50 mmHg.

As further illustrated, the time interval between times B and A is shown as 2.5 seconds, which is a default time interval. However, another predetermined time interval in the preferred range of 1-4 seconds may also be selected by a health care professional to achieve a preferred venous blood flow rate, based on the particular therapeutic application and medical needs of the recumbent user. According to an aspect of the present invention, means may be provided at the display 15 for allowing preselection of the desired time interval.

In the time interval between times B and A, a measurement (i.e., "sample") of the pressure in the first chamber is taken at least once. Based on this sample, the pressure in the first chamber is adjusted to the 50 mmHg level, if necessary. Adjustment of the pressure in a chamber can occur by either inflating the chamber if the pressure sample is too low or deflating the chamber if the pressure sample is too high. As illustrated, the pressure in the first chamber is adjusted from below 50 mmHg to above 50 mmHg at least once prior to time B.

At time D, which preferably occurs 2.5 seconds after time C, the third chamber is inflated to a third predetermined pressure level, shown as 40 mmHg. This occurs at time E. In addition, during the time interval between times D and C, samples of the pressures in the first and second chambers are taken at least once and the pressures are independently adjusted to the 50 and 45 mmHg levels, if necessary. As explained more fully hereinbelow with respect to FIG. 4, independent measurement of a pressure in a chamber occurs without depressurizing the other chambers. Furthermore, independent adjustment is achieved by pressurizing (or depressurizing) one chamber, while

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preventing pressurization (or depressurization) of the other chambers.

At time **F**, which preferably occurs 2.5 seconds after time **E**, the fourth chamber is inflated to a fourth predetermined pressure level, shown as 30 mmHg. This occurs at time **G**. The 50, 45, 40 and 30 mmHg levels establish a monotonically decreasing pressure gradient in a proximal direction along the limb of a user. It was determined by the inventors herein that a dual gradient of 5 mmHg between the first and second chambers and 10 mmHg between the third and fourth chambers is most preferred, however constant pressure levels in each chamber (i.e., no gradient) may also be possible if they are sequentially established.

In addition, during the time interval between times **F** and **E**, samples of the pressures in the first, second and third chambers are taken at least once and the pressures are independently adjusted to the 50, 45, and 40 mmHg levels, if necessary. And during the time interval between times **G** and **H**, samples of the pressures in each of the chambers are taken again and independent adjustments are made, if necessary. At time **H**, the chambers are simultaneously deflated. Time **H** preferably occurs 2.5 seconds after the pressure in the fourth chamber reaches a respective threshold pressure, and more preferably after the fourth chamber pressure has been established at 30 mmHg. Accordingly, times **B**, **D**, **F** and **H** preferably occur 2.5 seconds after times **A**, **C**, **E** and **G**, respectively. Alternatively, these time intervals may be preselected to be of varying length.

As illustrated, inflation of a first limb sleeve occurs 180° (e.g., 30 seconds) out of phase with respect to inflation of a second limb sleeve. In other words, only one sleeve is preferably inflated at a time (although both could be simultaneously inflated). Based on default settings which may be adjusted at the

display 15, the inflation cycle for the second sleeve (shown by dotted lines) begins 30 seconds after initiation of the first inflation cycle. Both the first and second inflation cycles preferably have default periods of 60 seconds, as illustrated.

According to an aspect of the present invention, 30 seconds also sets the maximum inflation time. Thus, a sleeve will automatically be deflated if time **H** does not occur before 30 seconds have elapsed from the initiation of inflation. Alternatively, the second inflation cycle could begin automatically at time **H** (i.e., after all chambers in the first sleeve have been inflated for the requisite 2.5 seconds), rather than at the 30 second mark. In this latter case, the inflation cycle period for each sleeve would typically vary from cycle to cycle, as would be understood by those skilled in the art.

Referring now to FIG. 3B, operations 70 performed by the system controller 10 during the first and second inflation cycles are summarized. In particular, the operations begin with the first sleeve and then an operation is performed to inflate the most distal chamber in the sleeve that is uninflated, Block 72. Thereafter, an operation is performed to determine whether a respective predetermined pressure in the chamber has been reached, Block 73. If not, pressurization is continued. However, if the respective predetermined pressure for the chamber has been reached, an interval timer is started, Block 74. Thereafter, the most distal chamber of the sleeve is preferably selected, Block 75, and then measured to obtain a pressure sample, while preventing depressurization of the other chambers, Block 76. Based on the respective pressure sample, an operation is then performed to adjust (+/-) the chamber pressure, Block 77. This is repeated for each of the next proximal chambers which have already been inflated,

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According to another aspect of the present invention, operations can also be performed in parallel with those operations illustrated by Block 72-83. In particular, a check is performed to determine if a prior inflation cycle has occurred, Block 71. If not, the normal operations (Blocks 72-82) are continued. If a prior inflation cycle has occurred, the pressure samples obtained from the prior cycle (or prior cycles) are averaged for each chamber, Block 84. Based on these averages, a check is performed to determine whether an excessive pressure condition has occurred, Block 85. If it has, subsequent inflation cycles are terminated until the system is reset, otherwise normal operations are continued. The system can be reset by accessing the display 15. According to this aspect of the present invention, instantaneous spikes in the pressures of one or more chambers can be compensated to prevent the occurrence of shutdown when a single or

relatively few aberrant pressure samples have been measured during an inflation cycle or during consecutive inflation cycles (e.g., 5). As described below with respect to FIG. 4, these operations are preferably performed by a system controller 10 having a preferred microprocessor-based control means 40. Control means 40 may also perform the function of detecting an occluded conduit and causing the display 15 to indicate a high pressure alert condition. For example, if a chamber inflating operation causes an excessive pressure (e.g., 100 mmHg) to be measured, control means 40 can automatically cause shutdown and alert the user.

Referring now to FIG. 4, a compression system according to one embodiment of the present invention will be described. According to this embodiment, the compression system comprises a system controller 10. The controller 10 has means for controlling transfers of air from a source of pressurized air 20 (e.g., a compressor) to inflatable chambers of first and second limb sleeves 22, 24, respectively. As illustrated, each limb sleeve (or combinations of single- and dual-chamber sleeves) comprises a plurality of inflatable chambers 22a-d and 24a-d. For purposes of illustration only, dotted-lines have been used to show pneumatic connections and solid-lines have been used to show electrical connections.

The system controller 10 further comprises first and second pluralities of feeder valves 26, 28 for enabling and disabling transfers of air from the pressurized air source 20 to the inflatable chambers 22a-d and 24a-d. In particular, each of the first plurality of feeder valves 26a-d is connected to respective ones of the chambers 22a-d and each of the second plurality of feeder valves 28a-d is connected to respective ones of the chambers 24a-d. The feeder valves 26a-d and 28a-d are preferably Model 35 Series

valves, which are publicly available from MAC Valves Inc. of Wixom, Michigan.

Independent inflation control means 40 is also provided for opening the feeder valves 26a-d, 28a-d one-at-a-time during a respective first or second inflation cycle. Control means 40 is preferably microprocessor-based. For example, an application specific integrated circuit (ASIC) or a multi-purpose microprocessor 42 may be provided to perform command and control operations, based on instructions contained in memory 44, such as programmable read-only memory (PROM). A multi-purpose microprocessor, such as a Motorola Semiconductor Corp., Model MC68HC11A1 microprocessor may be used. Control means 40 also preferably performs the function of regulating pressures in each of the inflatable chambers 22a-d and 24a-d.

Accordingly, regulation means is provided by the controller 10 for measuring the pressures in each of the chambers and for adjusting the pressures by intermittently inflating (and deflating) respective chambers to maintain pressure levels in the chambers at predetermined values, as illustrated by FIG. 3A. Means for performing chamber pressure measurements preferably comprises a pressure transducer 46. According to a preferred aspect of the present invention, only one pressure transducer for the entire system, as opposed to one transducer for each sleeve chamber, is required to independently measure the pressures in each of the chambers, without depressurizing any of the other chambers. The pressure transducer is preferably a Model MPX5050GP transducer, which is publicly available from Motorola Semiconductor Corp. of Phoenix, Arizona.

The system controller also preferably comprises intermediate valve means, shown as three-way intermediate valves 25 and 27. The intermediate valves are preferably Model 170 Series valves, which are also

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The controller of the present invention, also includes other modes of operation. As stated previously, the compression system of the present invention utilizes different types of compression sleeves that are configured to mount and conform to different body portions (i.e., calf, thigh, calf and thigh, foot, arm, forearm, torso, ect.). These differing compression sleeves require different compression cycles for proper treatment of the body portion to which they are mounted. Further, the compression system of the present invention also uses many different treatment methods for the same body portion based on the particular medical problems of the patient (i.e., deep vein thrombosis, circulatory disorders, lymphatic disorders, organ failure, joint problems, soft tissue trauma, wound healing through management of localized congestion, counteracting shock by minimizing pooling of blood, physical massage, pneumatic tourniquet ect). These differing treatment methods usually require different compression cycle patterns for inflating the compression sleeves. These differing compression cycles and the different treatment methods constitute different modes of operation for the controller.

In addition, at least one mode of operation

includes an operation to verify and calibrate the system. In this mode of operation, a special compression sleeve or a calibration tube and connector, not shown, having only a single inflatable chamber or tube connected thereto is used to verify/calibrate the pressure transducer 46. In this particular mode of operation, the appropriate feeder valves are opened by the controller to allow the pressure transducer 46 to be calibrated against a known pressure in the connected compression sleeve. The pressure of the transducer is displayed on the LCD display 15 and can be adjusted by the user to match the pressure in the sleeve or can be recalibrated by software in the microprocessor.

The different modes of operation of the present invention are typically stored in the controller memory 44 and are accessed by the microprocessor 42 to control the action of the feeder valves 26a-d and 28a-d. The modes of operation are defined by varying the number of chambers used, varying the amount of pressure in the sleeves, varying the pressurization times, and varying the sequence in which the compression sleeves are inflated. These modes of operation used by the microprocessor 42 may be either selected manually from the memory by the user through the display 15 or automatically by the use of a sensor 36.

In the automatic or non-user input mode, a sensor 36 is used to select the proper mode of operation. For instance, in one embodiment, the sensor 36 is used to determine whether a compression sleeve 22 or 24 is connected to the controller 10. The sensor 36 may also be used to determine whether more than one compression sleeve 22 or 24 is connected to the controller 40 for instances where two body portions (e.g., both legs) are to be treated. An example of these embodiments is shown in Figure 8, which illustrates a connecting devices 17a-b and connectors

58a-b. This system includes optical signal generators 60 that direct an optical signal to the indicators 62 of the connectors to the compression sleeves 22 and 24. If the compression sleeves are connected to the
5 connecting devices, the indicators 62 will reflect the optical signals and these reflected optical signals will be sensed by sensors 36. As shown in Figure 4, the controller 40 receives the sensed signals from the sensors 36 and provides pressurized air to both of the
10 compression sleeves 22 and 24 through the connecting devices 17a and 17b. However, if for example compression sleeve 24 is not connected to the connecting device 17b, the sensor will send a signal to the microprocessor that designates that the sleeve 24
15 is not connected to the connecting device 17b. The microprocessor will then configure the controller to prevent the flow of pressurized air to that connecting device 17b.

It is also advantageous in some embodiments
20 to reconfigure the mode of operation for differing compression sleeves. As stated previously, the compression sleeves may differ in many ways based on the part of the body they are configured to conform to or the particular treatment to be performed on the body
25 portion. For instance, in some embodiments the compression sleeves 22 and 24 may differ in the number of inflation chambers 22a-d and 24a-d. In this embodiment, the indicator 62 connected to the selected compression sleeve indicates either the number of
30 inflation chambers or the pressure cycle to be used for the desired treatment. This indication is sensed by the sensor 36 and provided to the controller 40. The controller 40 then automatically adjusts to one, two, three, four, ect. inflation chambers or adjusts the
35 cycle of pressure to the inflation chambers. Thus, the system can be configured automatically to perform several modes of operation without user input.

The mode of configuration may also be indicated by configuring the output ports of the feeder valves. For example, a blocking device may be used to restrict the air flow from one or more of the output valves, where the blocked output ports designate a particular mode of operation (blocking two of the output ports to designate that only two chambers are to be inflated). The mode of operation is determined by the controller by initially assessing the pressure associated with each output port to determine whether the port is blocked. Based on this assessment of the output ports the controller determines the proper mode of operation.

In particular, with reference to Figure 8 the output ports **17a-b** of Figure 5 are illustrated in greater detail. In this embodiment, these output ports are configured to mate to a plurality of connectors **58a-b** that are associated with compression sleeves designated to operate with different modes of operation. These output ports contain output connectors **57a-d** that are connected to the feeder valves and are configured to mate to the connectors **58a-b**. In this embodiment, a blocking device **59** may be used to select the mode of operation of the controller. In particular, a blocking device **59** may be placed in front of one of the output ports (e.g., **57b**). As such, the blocking device **59** restricts the flow of air through the port **57b**. The blocking device **59** may be of any material sufficient to restrict the flow of air in the output port. For example, the blocking device could be a plug disposed in the connectors **58a-b** and cover the output ports when the output connectors **17a-b** are connected to the connectors. Further, the blocking device may be just a flat surface disposed in the connectors **58a-b** or even an adhesive tape covering the output port.

To ascertain the mode of the system, the

controller initially determines the pressure on each port 57a-d. In particular, when the system is activated, the controller initially applies air flow through each of the feeder valves 26a-d to the output ports 57a-d. The blocking device 59 will restrict the flow of air through the output port 57b. The controller monitors the pressure associated with each output port 57a-d through the transducer. The transducer will sense a minimal pressure on the output ports 57a, 57c, 57d because they are not blocked by the blocking device 59. However, the transducer will sense a relatively high pressure on the output port 57b blocked by the blocking device 59 because the blocking device 59 has restricted the flow of air through the output port. Essentially, the blocked output port represents a logic one because of the high pressure and the open output ports represent a logic 0 because of the minimal pressure.

Based on the information from sensing the pressure of each output port, the control device will access memory and determine the mode of operation associated with the configuration of the blocked output port 57b. The controller then configures the system to operate in the selected mode.

As discussed above, the mode of operation may also be designated in this embodiment by blocking two or more of the output ports 57a-d or by blocking a selected combination of the output ports 57a-d.

In some embodiments of the present invention, the configuration of the system into the selected mode of operation is performed by use of a universal connecting device. Figure 9 illustrates one of the output ports 17a of Figure 5 in greater detail. In this embodiment, these output ports are universal connecting devices configured to mate to a plurality of connectors that are associated with compression sleeves that are designated to operate with different modes of

operation. In more detail, the universal connecting device contains a connector housing 70 for mating with a connector 58. A sensor 36 is operably mounted to the connector housing 70 and an indicator 62 is connected to the connector. The indicator 62 designates the selected mode of operation associated with the connector.

Figure 10 illustrates the operation of the universal connecting device. With reference to Figures 9 and 10, in **Block 100**, a connector 58 is mated to the connector housing 70. An indication is then provided from the indicator connected to the connector, which designates a selected mode of operation associated with the connector. (**Block 110**). This indication is sensed by the sensor 36. (**Block 120**). The sensor 36 provides the sensed signal to the microprocessor 42 of the controller 40. (**Block 130**). Finally, the controller configures the system to operate in the predetermined mode of operation designated by the indicator based upon the definition of the respective mode provided by the indicator. (**Block 140**).

Although the universal connecting device is illustrated herein in connection with a device for improving venous blood flow, this is for illustrative purposes only. It is contemplated that the universal connecting device can be used for any type of system. Therefore, the universal connecting device should not be limited to the embodiments shown.

As shown above, the universal connecting device of the present invention can be used to determine the selected mode of operation associated with a connector connected thereto. The universal connecting device can have many different embodiments, three of which are shown below as examples.

In one embodiment of the universal connecting device, the sensor 36 comprises a Hall Effect sensor for sensing an indication from the indicator. As

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commonly known, a Hall Effect sensor detects the presence of magnetic signals and provides a signal based on these sensed magnetic signals. For example, the north and south poles of a magnet generate differing magnetic fields. A Hall Effect sensor provides different voltage signals based on whether it senses a positive magnetic signal (i.e., north pole of a magnet) or a negative magnetic signal (i.e., south pole of a magnet) or when no magnetic signal is present (i.e., no magnet at all). This aspect of the Hall Effect sensor can be utilized to detect different modes of operation associated with connectors connected to the universal connecting device. Hall Effect sensors are publicly available from Micro Switch, a division of Honeywell, Inc.

Figure 11A illustrates an embodiment of the present invention including a Hall Effect sensor. In this embodiment, the indicator 62 is located in the connector 58 and comprises a plurality of magnets 64. As shown in Figure 11B, these magnets are either configured in a particular arrangement or are placed in a designated position, wherein the arrangement or the position corresponds to a predetermined mode of operation associated with the connector. In other words, either the placement or the configuration (i.e., respective polarity) of the magnets in the connector or a combination of both placement and configuration corresponds to a particular mode of operation for the system. Further, the absence of a magnet may also correspond to a particular mode. The placement and configuration of the magnets also correspond to a particular data point stored in the memory 42 of the controller, shown in Figure 4.

In operation, the Hall Effect sensor 36 senses the placement or configuration of the magnets and provides a signal to the controller 40 that represents the mode of operation associated with the

connector. The microprocessor 42 compares this sensed signal with the data stored in memory 44 and selects the data point that corresponds to the sensed signal. This data point is then used by the microprocessor 42 to configure the controller 40 for operating in the selected mode of operation. Thus, the controller 40 will properly control the action of the feeder valves 26a-d and 28a-d to provide pressurized air to the inflatable chambers of the compression sleeve and will also control the feeder valves to provide the correct cycle of pressurized air to the inflatable chambers depending on the designated treatment.

As stated above, the Hall Effect sensor 36 senses the configuration and placement of the magnets in the connector. For instance, in one embodiment a single magnet may be placed at different locations in the connector wherein each location signifies different modes of operation. In this embodiment, a Hall Effect sensor is placed at each possible location that the magnet may be placed. The Hall Effect sensor that corresponds to the placement of the magnet will provide a signal to the microprocessor. The microprocessor then compares the sensed signal to the data stored in memory 44 and configures the system to operate in the selected mode of operation.

Figure 11B illustrates another embodiment of the universal connector with a Hall Effect sensor. In this embodiment, a plurality of magnets 64 are configured such that their configuration designates a mode of operation associated with the connector 58. The configuration of the magnets relates not only to their position in the connector 58 but also to their presence (i.e., is there a magnetic signal present) and polarity (i.e., north or south pole). For instance, as illustrated in Figure 11B, the magnets 64 are arranged by polarity in the connector. The polarity of these magnets 64 are sensed by the Hall Effect sensors 36,

and these sensed signals are provided to the microprocessor 44 of the controller 40 which compares the sensed signals to the data in memory 42. Table 1, shown below, illustrates the different combinations of two magnets used as indicators in a connector.

Configuration		
Mode of Operation	Magnet 1	Magnet 2
1	No Magnet	No Magnet
2	No Magnet	North
3	No Magnet	South
4	North	No Magnet
5	South	No Magnet
6	North	North
7	North	South
8	South	North
9	South	South

Table 1

As seen from Table 1, two magnets can used to designate nine different modes of operation based on the presence and or configuration of the poles of the magnets.

These modes of operation can be stored in memory and retrieved based on the configuration of the magnets

As stated previously, some embodiments of the universal connecting device utilize an optical signal sensor to detect the mode of operation associated with a connector mated to the connecting device. With reference to Figure 9 two of these embodiments are illustrated. In the first embodiment, the universal connecting device of the present invention further

comprises an optical signal generator 60 and the indicator 62 connected to the connector 58 includes either a reflective or nonreflective material. The optical signal generator 60 directs an optical signal toward the indicator 62 of the connector 58 and the indicator 62 will reflect the signal if a reflective material is used or will not reflect the signal if a nonreflective material is used. Whether the indicator 62 reflects or does not reflect the optical signal indicates different modes of operation for the system. In this embodiment, the sensor 36 comprises an optical sensor that senses the optical signal reflected by the indicator 62 and provides a signal to the microprocessor 42 of the controller 40 designating whether a reflected signal was detected or not. Based on whether a signal was detected or not the microprocessor 42 determines the mode of operation associated with the connector 58 and configures the system.

As discussed in relation to the Hall Effect sensor, the indicator 62 of this embodiment may comprise a plurality of reflective and nonreflective strips that can be configured to provide different combinations for designating particular modes of operation much like the magnets shown in Table 1.

In another embodiment of the present invention, the indicator 62 comprises a material having a specified level of reflectivity that corresponds to an associated mode of operation. For instance, in this embodiment, the optical signal generator 60 directs an optical signal to the indicator 62 attached to the connector. The indicator 62 partially reflects the optical signal with a level of reflectivity that is associated with the selected mode of operation of the connector. This partially reflected signal is detected by the sensor 36, and the sensor provides the detected signal to the microprocessor of the controller 60.

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conduit ribbons 56, and then inserting respective male connecting members 52, at the source ends of the conduits, into each of the output ports 17a and 17b. Thereafter the controller is turned on by accessing the on/off switch 12. This causes the controller 10 and particularly control means 40 to perform various diagnostic start-up operations, such as performing a check, which is responsive to sensing means 36, to determine whether one or more of the sleeves is disconnected.

Control means 40 controls operations for inflating the first chamber 22a to 50 mmHg by providing a first control signal (e.g., logic 0) to feeder valves 26a and 28a-d and to the second intermediate valve 27. Second control signals (e.g., logic 1) are also provided to feeder valves 26b-d, along the solid control lines, as shown. Second control signals are also provided to the first intermediate valve 25 and to a source valve 32, which is connected to the source of pressurized air 20. These valves are preferably three-way, normally-open, solenoid controlled valves, as illustrated. Accordingly, the application of a second or "energizing" control signal to the solenoid of each valve causes the output of the valve to be directionally coupled to a first input, shown as opposite the input side of the valve. However, the application of a first or "deenergizing" signal to the solenoid of each valve causes the output to be directionally coupled to a second input (or vent), shown as orthogonal to the output side of the valve.

These initial operations will cause the source of pressurized air 20 to be pneumatically connected to the first chamber 22a and inflation will begin. Chambers 22b-d and chambers 24a-d are disconnected from the source and are not inflated at this time. In particular, feeder valves 26b-d will be held in an energized but blocking state, as shown by

the pneumatic termination (---|), and feeder valves
28a-d and the second intermediate valve 27 will be held
in a deenergized and open state. As shown, the feeder
valves 26a-d and 28a-d have been modified so that the
5 first input is plugged. In addition, an energizing
signal is also generated to open the source valve 32
and the first intermediate valve 25. A deenergizing
signal is also generated to open the feeder valve 26a,
which is now in a normally-open position and can accept
10 pressurized air from the source 20.

Because the volume of the first chamber 22a
will typically vary depending on the size of the sleeve
and limb (and also whether the sleeve is loosely or
tightly wrapped around the limb) control means 40 also
15 performs special startup control operations, which
typically occur during the first 5-10 inflation cycles
for a respective sleeve. Here, during the initial
inflation cycle for each sleeve, the controller
inflates each chamber for a respective predetermined
20 default time interval (retained in PROM 44) and then
takes a measurement to determine whether the default
time interval was long enough (or too long) to achieve
the desired pressure level. If the measurement is too
low, control means 40 will automatically increase the
25 time interval so that during the next inflation cycle,
the updated inflation time interval will be longer to
correspond to the actual time needed for this chamber
to inflate properly. These operations, which provide
real-time feedback, typically occur repeatedly for each
30 chamber during the first 5-10 inflation cycles or until
the system "levels-out" at the desired inflation times.
Because the respective inflation times are stored in
volatile memory 48, such as RAM, these operations will
need to be repeated every time the system is turned-on
or reset. The PROM 44 may also contain a maximum fill
35 time interval, so that if a chamber is not properly
inflated in that interval, control means 40 will

These special control operations will also
5 need to be performed if the user-selected pressure
levels, described above with reference to FIG. 2, are
greater than or less than the default pressure levels
of 50, 45, 40 and 30 mmHg. Moreover, if during the
course of operation, the user or health care
10 professional actuates the display 15 and adjusts the
default pressure levels to new values, these special
start-up control operations will be automatically
performed again to generate new inflation times and
adjust the system to the new pressure levels.

Control means **40** also regulates the pressure in the first chamber **22a** by adjusting it to the first predetermined pressure if the sample is outside an acceptable pressure tolerance. For example, a short inflating or deflating step can be performed to adjust the pressure in the first chamber **22a**. In order to deflate the first chamber **22a**, the second or energizing control signal can be temporarily removed from the first intermediate valve **25** in order to vent some of the air from the chamber through the feeder valve **26a**

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analogous operations are also performed by means 40 to inflate and regulate the second

In particular, deenergizing signals are sent at each of the feeder valves 26a-d and first chamber valve 25 so that the first sleeve 22 is in a deflated state. To begin inflation of the second chamber 24a, control means 40 provides energizing signals to open the source valve 32 and the second chamber valve 27 and also provides energizing signals to feeder valves 28b-d to maintain them in the inflated state. Accordingly, a connection is provided between source 20 and first chamber 24a at the start of the second inflation cycle.

As described above, means, such as a membrane switch 15 or an RS232 data port, may be provided to allow adjustment of the controller 10. In 2-, 3-, ..., N-chamber mode of operation may be achieved in either sleeve. For example, a controller 10 having a 2-sleeve/4-chamber default mode as described herein, can be converted to a 4-chamber system by selecting this mode at the controller 10.

Based on this selection, control means 40 performs normal operations for inflating fourth chamber 24d by continuously providing energizing signals to feeder valves 26d or 28d to maintain them in the inflated state. Similarly, four chamber operation in 2-sleeve and two chamber operation in the 4-chamber mode can be selected. In this mode, control means 40 would disable normal operations for inflating fourth chambers 24c-d, by continuously providing energizing signals to feeder valves 28c-d to maintain them in a blocking state during inflation cycle.

Referring now to FIG. 5, the valve manifold 17 is illustrated in greater detail. In particular, first and second output ports 17a-b and associated feeder valves 26a-b are provided for pneumatically

operating feeder valves 26a-b in the conduits 54. The control means 40 provides control signals to feeder valves 26a-d and intermediate valves 25, 27, 29, as shown. The compression system 30 in the present embodiment is a positive displacement pump, but has a variable flow rate fully adjustable by the controller 10. The controller 10 provides regulated air from an air source 20' to a plurality of chambers 24a-d during respective inflation cycles. The air source 20' at vent 21 is being measured by a pressure transducer 23 inflated to a pressure 24. The illustration shows pneumatic control lines used to show the operation of controller 10' in controlling pluralities of chambers 24a-d by inflating and disabling air source 20' to chambers 24a-d. Each of the first and second chambers 24a and 24d comprises a pair of valves (M26a), (F26b), (F28a, M28a), (F28b, M28b), (F28c, M28c), (F28d, M28d). The use of a single air source 20' provides a number of advantages. The normally-open valves 26a-b, 28a-d, 4, as described

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Control means **40'**, which is operatively

connected to the filling, monitoring and intermediate valves, is also provided for inflating a first inflatable chamber 22a of the first limb sleeve 22 by disposing the corresponding filling valve (e.g., F26a) in an open state and the other filling valves F26b-d and F28a-d in their respective normally-closed states. During inflation of the first inflatable chamber 22a, the corresponding first monitoring valve (e.g., M26a) is also disposed in a normally-open state so that the pressure in the first inflatable chamber 22a can be monitored (i.e., measured or sampled) in real time as it is being inflated and thereafter when the first inflatable chamber 22a is fully inflated and the corresponding filling valve (e.g., F26a) has been closed. Monitoring of the pressure in the first inflatable chamber 22a is preferably achieved by also disposing the corresponding three-way intermediate valve (e.g., 29) in its second open state (in response to an energizing logic 1 signal) so that the pressure transducer 46 embodied in the control means 40' becomes pneumatically coupled to the first inflatable chamber 22a and performs a measurement of the pressure therein. Thus, in contrast to the first embodiment of FIG. 4, the pressure in a chamber can be continuously measured as the chamber is being inflated to its respective predetermined pressure. This provides real-time feedback of the chamber pressure. Preferably, this real-time feedback is used by the control means 40' to adjust the inflation time of the respective chamber during the current or subsequent inflation cycle(s). The amount of time needed to measure the pressure in a chamber after the respective filling valve closes can also be reduced since the pneumatic connecting lines between the respective monitoring valve and the pressure transducer 46 will already be at least partially pressurized at the respective chamber pressure.

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CHAMBER	VALVE											
	F26a	M26a	F26b	M26b	F26c	M26c	F26d	M26d	29	31	F28 a-d	M28 a-d
FILL 22a	O	O	C	C	C	C	C	C	O	V	C	O
MONITOR 22a	C	O	C	C	C	C	C	C	O	V	C	O
FILL 22b	C	C	O	O	C	C	C	C	O	V	C	O
MONITOR 22b	C	C	C	O	C	C	C	C	O	V	C	O
FILL 22c	C	C	C	C	O	O	C	C	O	V	C	O
MONITOR 22c	C	C	C	C	C	O	C	C	O	V	C	O
FILL 22d	C	C	C	C	C	C	O	O	O	V	C	O
MONITOR 22d	C	C	C	C	C	C	C	O	O	V	C	O

TABLE 2

CHAMBER	VALVE											
	F28a	M28a	F28b	M28b	F28c	M28c	F28d	M28d	29	31	F26 a-d	M26 a-d
FILL 24a	O	O	C	C	C	C	C	C	V	O	C	O
MONITOR 24a	C	O	C	C	C	C	C	C	V	O	C	O
FILL 24b	C	C	O	O	C	C	C	C	V	O	C	O
MONITOR 24b	C	C	C	O	C	C	C	C	V	O	C	O
FILL 24c	C	C	C	C	O	O	C	C	V	O	C	O
MONITOR 24c	C	C	C	C	C	O	C	C	V	O	C	O
FILL 24d	C	C	C	C	C	C	O	O	V	O	C	O
MONITOR 24d	C	C	C	C	C	C	C	O	V	O	C	O

TABLE 3

The drawings and specification disclose typical preferred embodiments of the present invention and, although specific terms are employed, they are used in a generic and descriptive sense only and not for purposes of limitation, the scope of the invention being set forth in the following claims.